

**REMARKS-GENERAL**

1. The Applicant expresses his appreciation to the Examiner for the diligence shown in the examination of this application.
2. Reconsideration of the application as amended is respectfully requested.
3. Claims 10, 13, 19, 21, 22 and 31 have been amended to overcome rejections cited in the office action mailed 7/02/03, more particularly recite the invention, and to correct editorial errors. Claim 28 is cancelled. These claims are all submitted to be patentable over the cited references because they (1) recite novel structure and thus distinguish physically over every reference (section 102) and (2) the physical distinctions effect new and unexpected results, thereby indicating that the physical distinctions are unobvious under section 103. The Applicant submits that no new matter was introduced as a result of the claim amendments. The current claims of record are claims 10-13, 17-27 and 29-32.
4. Claims 10-13, 17-20 and 32 were rejected under 35 U.S.C. Section 112 as being indefinite and failing to particularly point out and distinctly claim the subject matter. In regards to independent claim 10, the Applicant takes exception to the basis of the rejection as stated below. Dependent claims 13 and 19 were amended to overcome the 35 U.S.C. Section 112 rejections. The Applicant believes that the rejection applied to dependent claim 32 was intended to be for dependent claim 31. Claim 31 was amended as suggested by the Examiner.
5. In regards to claim 10, it is not clear that the Examiner's assertion that "both the sample chamber as well as the area defined by --- define a reduced diameter sample chamber" when the sample chamber is itself defined by this language. The Applicant respectfully submits that the limitation "the seal surface of the insert, reduced-diameter portion, and a bottom portion of the vessel defining a reduced-volume sample chamber as

compared to the sample vessel alone” is definite and clear in regards to the claimed subject matter, and complies fully with the requirements of 35 U.S.C. section 112.

6. Claims 10 and 21-25 were rejected under 35 U.S.C. section 102(b) as being anticipated by Classon et al. Classon et al. discloses a self-filtration cap for filtering and storing liquid which can be then removed from the device for analysis. The device utilizes a top cap and a filter cap, creating a storage area when the top cap and the filter cap are sealed together.

**The Claims, as amended, Recite Novel Physical Features And Structure And Hence Make The Claims Patentable Under Section 102(b).**

7. In regards to the rejections of independent claims 10 and 21 (item 2 of the Office Action), Classon et al. does not disclose a reduced-diameter portion having a close fit with an outside diameter of a penetrating sample deposit/extraction device. Neither does Classon et al. disclose a penetrating sample *deposit* device. Rather the fluid pressure caused by the “piston action” (column 8, line 26-34) of the needle drive 88 and housing 85 act only to *extract* fluid, rather than extract *and* deposit as disclosed by the present invention.

8. Additionally, in regards to dependent claim 22, Classon et al. does not disclose the *sample deposit/extraction element* as being the motive for transferring the sample, but rather the “piston action of the filtration device” (Col 8, lines 26-28). Classon et al. discloses no method of depositing fluid via the needle 86.

9. Additionally, in regards to dependent claim 23, Classon et al. does not disclose an adsorbent element in the device. Nor, in regards to dependent claim 24, does Classon et al. disclose an absorbent element in the device.

**The Novel Physical Features Of The Claims, As Amended, Provide New and Unexpected Results And Hence Should be Considered Unobvious, Making the Claims Patentable Under Section 103.**

10. In regards to the obviousness rejections over Classon et al. of dependent claims 11 and 26 (item 6 of the Office Action), the Applicant submits that the process as claimed provides new and unexpected results and is patentable under U.S.C. Section 103(a) since by inserting the needle in the device *before* insertion of the device into the sample vessel allows the needle to move and reposition the device as well as insert it into the vessel. The present invention allows precise positioning, moving and relocating the insert and even the sample vessel itself by use of the sample needle. *Classon et al. neither suggests nor discloses such a process, nor does the structure of the Classon et al. device support such a feature.*

11. In regards to dependent claim 11, Classon et al. does not disclose “positioning a penetrating sample deposit/extraction element above the insert and inserting the penetrating sample deposit/extraction element through the septum seal, the conical guide, and into the reduced-diameter portion is performed before the step of inserting a volume-adjusting insert into a sample vessel”. Rather, Classon et al. specifically states that “an assembled filter device 10’ is slid into the vial above the sample” (Col. 7, lines 58-63) *before* “the vial then is inserted into position in a sample handling device such as an auto sampler” (Col 8, lines 4-8). It is the auto sampler of Classon et al. which comprises needle 86.

12. Neither does reversal of the steps of the Classon et al. teachings, as suggested by the Examiner, provide the feature of the current invention since Classon et al. does not even disclose use of the needle to perform the initial insertion. The “close fit” feature providing alignment of the device with the needle provides this ability in the present invention as claimed.

13. In regards to the obviousness rejection of claims 12, 13, 17 and 18 (item 7 of the Office Action) the Applicant submits that the combination of the sample vessel of Classon et al. with the bottom extraction hole taught by both Kedar et al. and Donald is inoperative and the 35 U.S.C. 103(a) rejection of these claims based on Classon et al. in view of Kedar et al and/or Donald is not appropriate. Motive force for fluid extraction of the Classon et al. device is provided by the *piston action of the device* (Col 8, lines 26-28). Addition of an extraction hole as taught by Kedar et al. and/or Donald in vessel 100 would prevent hydraulic pressure from being produced by this piston action and therefore prevent fluid extraction as taught by Classon et al.

14. The Applicant submits that the rejection of claims 11 and 26 under 35 U.S.C. 103(a) as being unpatentable over Classon et al. in view of Stevenson et al. (item 8 of the Office Action) is inappropriate as *neither Classon et al nor Stevenson et al. disclose or suggest "positioning the insert for insertion into the vessel is performed with the sample deposit/extraction element through frictional engagement of the sample deposit/extraction element and the septum seal"*. Additionally, neither Classon et al. nor Stevenson et al. disclose even movement of the "insert" *within the vessel* by frictional engagement of the needle and septum seal, but rather insertion is made by a blocking action of a needle housing 85 (or collar 106) of Classon et al. and a collar 14 of Stevenson et al. against the cap 12 of Classon et al. or stopper 12 of Stevenson et al. Therefore, even if the references are combined as suggested by the Examiner, the combination still lacks the features of the claimed invention.

15. In regards to the rejection of claims 19, 20, and 27-30 based on the combination of Classon et al. and Stevenson et al., the Applicant submits that the characterization of collar 14 as an "insert" as applied to the combination is in error. The collar 14 of Stevenson et al. is simply a "pushing device" for stopper 12 and has not even the minimal features of an insert as defined by the invention. It does not seal with the vessel, it has no fluid chambers or interfaces, no septum seal, no capability to define a "reduced-volume sample chamber and cannot be justified as such. Functionally, collar 14 of Stevenson et al. is the same as needle housing 85 and collar 106 of Classon et al.

16. The Applicant submits that the rejection of claim 31 based on the Examiner's assertion that Stevenson et al. discloses a first septum seal and a second septum seal is in error. Only a single septum seal (top face of stopper 12) is disclosed by Stevenson.

#### **Unsuggested Combination**

17. None of the cited and relied-upon references suggest that the features of the teachings be combined as suggested by the Examiner.

#### **Multiplicity of Steps Required**

18. The combinations, if undertaken, would require a series of separate, awkward combinative steps that are too involved to be considered obvious.

#### **Combination Still Lacking Novel Features**

19. Even if the references are combined, the resulting combination would still not result in the present invention. None of the combinations suggested by the Examiner produce a close fit between the needle and the reduced-diameter portion. Such a fit provides the necessary alignment for precise positioning, moving and relocating the insert and even the sample vessel itself by use of the sample needle. *None of the references even suggest such an important feature.*

### **The Cited But Non-Applied References**

20. These subsidiary references have been noted and reviewed, but are submitted to be less relevant than the relied upon references.

### **The Dependent Claims Are A-fortiori Patentable**

21. The dependent claims add additional novel features and thus are submitted to be, a-fortiori, patentable.

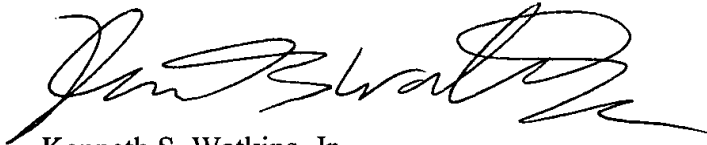
### **Allowance Requested**

22. For the above reasons, the Applicant's Agent submits that the Sample Collection and Processing Device disclosed and claimed in the present application is not taught by any of the references of record, taken either alone, or in combination. Therefore, allowance of the present application is in order and respectfully requested.

### **Request For Constructive Assistance**

The undersigned has made a diligent effort to amend the claims of this application so that they define novel structure and render the claimed structure unobvious because it produces new and unexpected results. If for any reason the claims of this application are not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to MEP 707.07(j) and MEP 706.03 (d) in order that this application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully,



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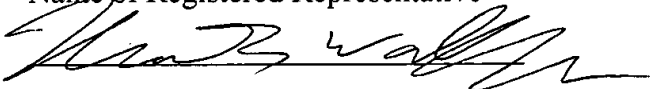
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